Notice of Allowability	Application No.	Applicant(s)	
	09/823,213	DUNLAVEY, MICHAEL R.	
	Examiner	Art Unit	
	Kandasamy Thangavelu	2123	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *May 23, 2005*.

2. ☒ The allowed claim(s) is/are *1-3,5,6,9-12,14-17 and 19-25*.

3. ☒ The drawings filed on *30 March 2001* are accepted by the Examiner.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☒ Other *See Continuation Sheet*. (See below)

Continuation of Attachment(s) 9. Other: Clean copy of the allowed claims .

KC

DETAILED ACTION

Introduction

1. This communication is in response to the Applicant's communication dated May 23, 2005. Claims 1-3, 5-6, 9-12, 14-17 and 19-25 of the application are pending.

Drawings

2. The drawings submitted on March 30, 2001 are accepted.

Examiner's Amendment

3. Authorization for this examiner's amendment was given in a telephone conversation by Mr. Kent Tobin on August 1, 2005.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to the applicants, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

4. In Claim 1:

Replace claim 1 with:

1. A system for clinical trial simulation, comprising:

an interface having a fixed form module and a trial definition language free form module, the interface configured to receive information that describes a trial protocol comprising a plurality of schedules for a clinical trial simulation and to receive information to dynamically modify trial schedules to simulate dosage adjustment protocols during trial in response to disease progression;

a translator having a protocol parser and a code generator, the protocol parser configured to parse the trial protocol, the code generator configured to generate source code in a high level general purpose programming language;

a compiler having a code parser and a machine code generator, the compiler configured to compile the generated source code into an executable program comprising a plurality of programmable state machines, each state machine corresponding to one of the plurality of schedules, the state machines dynamically determining dosage adjustment protocols and schedule parameters in response to information generated in simulation based on the disease progression; and

a controller communicatively coupled with the interface, the translator, and the compiler, the controller configured to run the executable program including the plurality of programmable state machines, according to a time queue.

In Claim 3:

Replace claim 3 with:

3. The system of claim 2, wherein the free form module is configured to receive trial protocol information in a trial design language, conforming to a predefined structured language format designed for clinical trial simulation.

In Claim 9:

Replace claim 9 with:

9. A method for clinical trial simulation, comprising:

receiving trial protocol information that describes a clinical trial simulation in a fixed form and a trial definition language free form;

receiving information to dynamically modify trial schedules to simulate dosage adjustment protocols during trial in response to disease progression;

arranging the trial protocol information into a plurality of schedules;

translating the plurality of schedules into a high level general purpose programming language;

compiling the translated plurality of schedules into an executable program comprising a plurality of state machines, each state machine corresponding to one of the plurality of schedules, the state machines dynamically determining dosage adjustment protocols and schedule parameters in response to information generated in simulation based on the disease progression; and

executing the program including the plurality of state machines, according to a time queue as part of the clinical trial simulation.

In Claim 10:

Replace claim 10 with:

10. The method of claim 9, wherein the receiving step comprises:

receiving trial protocol information that conforms to a structured format; and

receiving trial protocol information in a trial design language, conforming to a predefined structured language format designed for clinical trial simulation.

In Claim 14:

Replace claim 14 with:

14. A computer readable medium having stored thereon one or more sequences of instructions for causing one or more microprocessors to perform the steps for simulating a clinical trial, the steps comprising:

receiving trial protocol information that describes a clinical trial simulation in a fixed form and a trial definition language free form;

receiving information to dynamically modify trial schedules to simulate dosage adjustment protocols during trial in response to disease progression;

arranging the trial protocol information into a plurality of schedules;

translating the plurality of schedules into a high level general purpose programming language;

compiling the translated plurality of schedules into an executable program comprising a plurality of state machines, each state machine corresponding to one of the plurality of schedules, the state machines dynamically determining dosage adjustment protocols and schedule parameters in response to information generated in simulation based on the disease progression; and

executing the program as part of the clinical trial simulation including the plurality of state machines, according to a time queue.

In Claim 15:

Replace claim 15 with:

15. The computer readable medium of claim 14, wherein the receiving step comprises:

receiving trial protocol information that conforms to a structured format; and

receiving trial protocol information in a trial design language, conforming to a predefined structured language format designed for clinical trial simulation.

In Claim 19:

Replace claim 19 with:

19. A system comprising a microprocessor, a persistent storage area, a volatile storage area and a communication means, the system including an execution area configured to simulate a clinical trial by performing the following steps:

receiving trial protocol information that describes a clinical trial simulation in a fixed form and a trial definition language free form;

receiving information to dynamically modify trial schedules to simulate dosage adjustment protocols during trial in response to disease progression;

managing the trial protocol information into a plurality of schedules, the plurality of schedules comprising a dosing schedule and an observation schedule;

translating each of the plurality of schedules into a high level general purpose programming language;

compiling the translated schedules into an executable program, comprising a plurality of programmable state machines, each state machine corresponding to a discrete one of the plurality of schedules, the state machines dynamically determining dosage adjustment protocols and schedule parameters in response to information generated in simulation based on the disease progression; and

executing the program as part of the clinical trial simulation including the plurality of state machines, according to a time queue.

A clean copy of the amended claims is attached.

Reasons for Allowance

5. Claims 1-3, 5-6, 9-12, 14-17 and 19-25 of the application are allowed over prior art of record.

6. The following is an Examiner's statement of reasons for the indication of allowable subject matter:

The closest prior art of record shows:

(1) a computer assisted system and method for development of new medical interventions for diseases; the system includes modules for discovering proposed interventions, designing clinical trials, performing pharmacoeconomic analysis and illustrating disease progression for patients over time; the clinical trial is designed based on the underlying disease process, how patient attributes affect it, and how the proposed intervention, the disease biology and the patient attributes interact; the analyses are based on data generated by the models that simulate the disease process at cellular and subcellular levels; the estimate of the disease progression is a model of the disease outcome over time within a given patient type; the system uses the locus of change information and intervention information to simulate clinical trials; the clinical trials explorer sends the results of the clinical trial simulations to the pharmacoeconomic analyzer to evaluate the outcome for a particular type of patients (**Herren et al.,** U.S. Patent 6,108,635);

(2) a system software for design, simulation and implementation of manufacturing processes involving programmable logic controller (PLC); the PLCs are programmed using ladder logic where the instructions are represented graphically using contacts and coils;

templates and parametrizable control assemblies define the control information; the template language includes different kinds of module specifications that can be used to accommodate different operational circumstances; the control logic is compiled into PLC execution code; when linked to the control mechanisms correctly, the execution code causes the specified manufacturing processes to be performed; simulation is used to design and verify the programmable logic controllers; (**Hoskins et al.,** U. S. Patent 6,268,853);

(3) a system and method for managing clinical trial data by dynamically generating at a server, a data entry form to be displayed at a client; the data entry form is generated in a SGML derived language; the form is generated from a protocol database and a context received from the client and is populated from the data in the database; templates based on the protocol database comprise several frames; if the trial protocol changes during the trial, the generated form is based on the protocol active at the time the data was entered into the form; the clinical trial protocol specifies the exact timing and nature of the measurements and interventions to be performed on each patient; the protocol's time-line lists a series of events, where the data are collected from the study patient (**Bleicher et al.,** U.S. Patent 6,820,235); and

(4) a network communication protocol concept is initially designed and simulated on a simulation tool; system designers generate modules representing new network protocols for evaluation on a simulation tool; the simulation tools enable the user to specify various nodes and link characteristics; the functional aspects of the nodes are indicated in the form of finite state machines that utilize the software modules to simulate the node functions; the modules are typically implemented in C/C++ programming language; modules modeling the behavior of the

target system for system simulation are translated into software modules for execution on a target platform (**Whitehill et al.,** U.S. Patent 6,708,329).

None of these references taken either alone or in combination with the prior art of record discloses a system, a method and a computer readable medium storing sequences of instructions for clinical trial simulation, specifically including:

"an interface having a fixed form module and a trial definition language free form module, the interface configured to receive information that describes a trial protocol comprising a plurality of schedules for a clinical trial simulation and to receive information to dynamically modify trial schedules to simulate dosage adjustment protocols during trial in response to disease progression";

"a translator having a protocol parser and a code generator, the protocol parser configured to parse the trial protocol, the code generator configured to generate source code in a high level general purpose programming language"; and

"a compiler having a code parser and a machine code generator, the compiler configured to compile the generated source code into an executable program comprising a plurality of programmable state machines, each state machine corresponding to one of the plurality of schedules, the state machines dynamically determining dosage adjustment protocols and schedule parameters in response to information generated in simulation based on the disease progression".

7. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Kandasamy Thangavelu whose telephone number is 571-272-3717. The examiner can normally be reached on Monday through Friday from 8:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Leo Picard, can be reached on 571-272-3749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to TC 2100 Group receptionist: 571-272-2100.

Paul L. Rodriguez 8/5/05

Primary Examiner
Art Unit 2125

K. Thangavelu
Art Unit 2123
August 1, 2005